PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Steve Kangas**
Application No.:	**10/658729**
Filed:	**September 9, 2003**
Patent No.:	**7544381**
Issue Date:	**June 9, 2009**
For:	**Lubricious Coatings for Medical Device**
Examiner:	**Cachet I. Sellman**
Group Art Unit:	**1792**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-10814-US01

Petition Requesting Reconsideration of Dismissal of Application for Patent Term Adjustment

Applicant herein requests withdrawal of the Office's Dismissal of Applicant's Petition for Patent Term Adjustment and requests calculation of the Adjustment pursuant to *Wyeth v. Dudas,* 88 USPQ2d 1538 (D.D.C. 2008) and *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010) as requested in Applicant's previous petition. This Petition is sought under 37 CFR 1.181(a)(3) or, in the alternative, 37 CFR 1.183.

Applicant previously submitted a Petition requesting Patent Term Adjustment under 37 CFR 1.705 pursuant to the decision in *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008), on August 10, 2009. Applicant further requested that a decision regarding Applicant's request be held in abeyance pending final adjudication of the *Wyeth* case. In response, on November 25, 2009, the Office of Petitions dismissed Applicant's Petition alleging, *inter alia*, "[t]hat there is no specific regulatory provision for requesting that a petition under 37 CFR 1.705(d) be held in abeyance."

The Office's decision to dismiss Applicant's request was premature, erroneous, and an abuse of Patent Office discretion. The decision was contrary to law, as discussed below. Pursuant to 37 CFR 1.181(a)(3) or, in the alternative, 37 CFR 1.183, Applicant therefore requests that the Office withdrawal the dismissal of Applicant's Petition and grant Applicant the relief

provided under *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008) and *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010).

The Office's decision to dismiss was premature. The Office of Petitions refused to hold Applicant's Petition in abeyance on the grounds that it has no regulatory authority to hold such petitions in abeyance. Applicant disagrees on several grounds. The USPTO, as a regulatory agency, is charged with responsibility for decisions regarding the management and administration of its operations. To that end, 35 USC 1(a) states:

> **35 U.S.C. 1 Establishment.**
> (a) ESTABLISHMENT.— The United States Patent and Trademark Office is established as an agency of the United States, within the Department of Commerce. In carrying out its functions, the United States Patent and Trademark Office shall be subject to the policy direction of the Secretary of Commerce, but otherwise shall retain responsibility for decisions regarding the management and administration of its operations and shall exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with this title and applicable provisions of law. Those operations designed to grant and issue patents and those operations which are designed to facilitate the registration of trademarks shall be treated as separate operating units within the Office.

The responsibility referred to in 35 USC 1(a) includes assigning case loads and determining when petitions are reviewed. It is not believed that specific regulations are necessary to govern the details of the day-to-day operation of the USPTO. Note that the MPEP is essentially a compilation of Patent Office procedure, much of which is not expressly provided for under the regulations. As such, even without specific regulatory authority, Applicant contends that it is within the discretion of the USPTO to hold a decision on a petition in abeyance while a controlling legal issue is pending in court.

We further note that the MPEP provides for at least one situation in which a petition may be held in abeyance, not withstanding the lack of specific regulatory authority. MPEP 724.06 states:

> The decision on the petition to expunge should be held in abeyance until the application is allowed or an Ex parte Quayle action, or a Notice of Abandonment is mailed, at which time the petition will be decided. However, where it is clear that the information was submitted in the wrong application, then the decision on the petition should not be held in abeyance.

The District court in *Wyeth v. Dudas*, 88 USPQ2d 1538, had already determined that non-overlapping 3 year dates and 14 month dates must both be taken into account prior to the filing of Applicant's previous Request for Adjustment. In the interim period between the ruling of district court in *Wyeth* and disposition of the case on appeal, it made no sense to force other patentees to file cases under 35 USC §154(b) to preserve their rights. However, dismissing Applicant's request to hold their petition in abeyance would have necessitated this course of action. Forcing Applicant to file a case under § 154(b) multiplies litigation defense costs of the Office and unnecessarily increases the patentees' expenses in obtaining their patent rights. A simple public announcement that the Office would have held all patent term requests in abeyance until a final decision on the *Wyeth* appeal would have allowed the USPTO to advance its position in the appeal without harming patentees. Rational workload management considerations within the USPTO and general equitable considerations of fairness to patent owners, both weighed heavily in favor of the Office deferring consideration of Applicant's previous request for Adjustment.

Moreover, the Office's dismissal of Applicant's petition was an abuse of discretion. The Administrative Procedure Act prohibits agency action that is "not in accordance with law." The District Court in *Wyeth v. Dudas* had ruled the Office's interpretation of §154(d) to be "a construction [that] cannot be squared with the language of §154(b)(1)(B)." Thus, the position of the Office on periods of overlap under 154 is "not in accordance with law" within the meaning of the Administrative Procedure Act. The Office had no legal authority to decide a petition for term adjustment using the statutory construction advanced by the Office in the *Wyeth* case. Simply deciding to issue a decision on Applicant's previous petition while the *Wyeth* case was on appeal, using the Office's construction of §154 that it used in the *Wyeth* case, would be arbitrary and capricious, given the fact that the Office was on notice that its construction was wrong as a matter of law (which is now affirmed by the Federal Circuit). The Office's decision

to deny Applicant's request therefore constituted another violation of the Administrative Procedure Act.

Finally, Applicant's requests (previous and current) specifically impact a property right that the Applicant is legally entitled to. The due process clause of the U.S. Constitution is violated when the Office decides to deprive patent owners of term under a statutory construction that has been ruled to be contrary to law.

The Office did not have authority under law or the U.S. Constitution to issue a decision denying Applicant's request unless and until it obtained a reversal of the District Court's holding in the *Wyeth* case. It did, however, have the authority to defer decision on that request. In light of the foregoing, the Office improperly failed to hold Applicant's request in abeyance pending a final disposition on the *Wyeth* case. Failing to hold Applicant's Petition in abeyance, as requested, is therefore an abuse of discretion.

Moreover, Applicant's basis for filing their previous request for Patent Term Adjustment has now been upheld by a panel of Federal Circuit judges. *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010) (affirming the district court decision).

Consequently, Applicant is entitled to the relief sought in Applicant's petition filed on August 10, 2009, a copy of which is included herewith and incorporated herein by reference. Also included herewith is the Office of Petitions' Decision dismissing Applicant's previous request.

In light of the improper dismissal of Applicant's previous petition, Applicant is requesting that this petition be granted in accordance with 37 CFR 1.181(a)(3) – invoking the supervisory authority of the Director in appropriate circumstances. The events leading to the immediate Petition are believed to constitute "appropriate circumstances" pursuant to 37 CFR 1.181(a)(3). The Office prematurely decided Applicant's previous petition and abused its discretion in doing so.

In the event that the Office believes that this petition does not fall under 37 CFR 1.181(a)(3), Applicant requests that this Petition be considered, and in-the-alternative, under 37 CFR 1.183. Applicant again asserts that the extraordinary events leading to this Petition constitute an appropriate basis for invoking 37 CFR 1.183.

Finally, this Petition is believed timely. The Office of Petitions dismissed Applicant's previous petition on November 25, 2009 and this Petition is being submitted on January 25, 2010 – two months from the date of mailing of the Office's dismissal. *See* 37 CFR 1.181(f).

Conclusion

In sum, Applicant's previous request is believed to be in accordance with the rulings in *Wyeth v. Kappos* and *Wyeth v. Dudas* and the Office's dismissal of Applicant's previous petition is believed improper. Applicant therefore requests that the Patent Term Adjustment be corrected to show an adjustment of **1652** days, as previously requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 25, 2010

By: /Jonathan Grad/
Jonathan Grad
Registration No.: 41795

6640 Shady Oak Rd., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001
f:\wpwork\mjm\10814us01_pet_20100125.doc